K012517

NOV 01 2001

510(k) Summary
for
CEREC® inLab and
CEREC® Scan Dental Restoration Milling Machines

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: August 3, 2001

2. DEVICE NAME

Proprietary Name:	CEREC® inLab and CEREC® Scan
Common/Usual Name:	Ceramic Dental Restoration Systems
Classification Name:	Impression Material

3. PREDICATE DEVICES

CEREC® 3 Ceramic Dental Restoration System with Scanning Milling Machine (K994172)

4. INTENDED USE

The CEREC® inLab and CEREC® Scan Dental Restoration Milling Machines are intended to be used in the computer-aided design and milling of ceramic dental restorations, including inlays, onlays, veneers, crowns (full and partial), crown caps and bridge frameworks.

The design and milling of bridge frameworks is the only new intended use and is the subject of this 510(k) Premarket Notification.

5. DEVICE DESCRIPTION

The CEREC® inLab and CEREC® Scan are identical stationary dental milling units consisting of the same hardware, software, and operating instructions. The table-top rectangular housing encases the motors, mechanical gears, position sensors, and the milling chamber. The milling chamber contains the laser scanner, two grinding burrs and the spindle for the ceramic block. The milling process is driven by electrical DC motors and stepper motors operating under microprocessor control. The laser scanner, mounted within the milling chamber, is used to scan impressions or models of the tooth or teeth. The scanned data is then transferred to a PC computer either via an RS232 interface cable connected to the serial interface port at the rear of the milling machine or via an optional wireless module. The PC contains the software that is used by the dentist or the dental technician to design the restoration from the scanned data. The restoration is then milled from a ceramic block in the milling chamber under microprocessor control using the design parameters.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The CEREC® inLab and CEREC® Scan are substantially equivalent to CEREC® Scan that was cleared for marketing as part of the CEREC® 3 Ceramic Dental Restoration System under K994172. The main difference between the current CEREC® Scanning Milling Machines and the previous model is the additional capability of producing bridge framework restorations. However, the process for producing bridge frameworks is the same as for the other CEREC® restorations. The initial impression of the teeth at issue is made using traditional procedures and materials. The impression is fixed onto the spindle in the milling chamber, and the laser scanner is used to scan the impression. The CEREC® 3 software is then used to design the restoration based on the scanned impression. The resulting design parameters are used to mill the final restoration from the ceramic block.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 01 2001

Sirona Dental Systems GmbH
C/O Ms. Sheila Hemeon-Heyer
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K012517
Trade/Device Name: Cerec Inlab and Cerec Scan
Regulation Number: 872.3660
Regulation Name: Ceramic Dental Restoration Systems
Regulatory Class: II
Product Code: ELW
Dated: August 3, 2001
Received: August 6, 2001

Dear Ms. Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012517

510(k) Number (if known): NOV 0 1 2001

Device Name: CEREC® inLab and CEREC® Scan Dental Restoration Milling Machines

Indications For Use:

The CEREC® inLab and CEREC® Scan Dental Restoration Milling Machines are intended to be used in the computer-aided design and milling of ceramic dental restorations, including inlays, onlays, veneers, crowns (full and partial), crown caps and bridge frameworks.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012517

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)